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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/538,515

09/12/2007

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12684.15USWO

2315

23552 7590 06/10/2010
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EXAMINER

YOUNG, RACHEL T

ART UNIT

PAPER NUMBER

3771

MAIL DATE

DELIVERY MODE

06/10/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/538,515	Applicant(s) WALDNER ET AL.	
	Examiner RACHEL T. YOUNG	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment

1. This office action is responsive to the amendment filed on 3/1/10. As directed by the amendment: claims 1-19 have been amended, no claims have been canceled, and no new claims have been added. Thus, claims 1-19 are presently pending in the application.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. (6,851,626 B2) in view of Denyer et al. (6,584,971 B1).

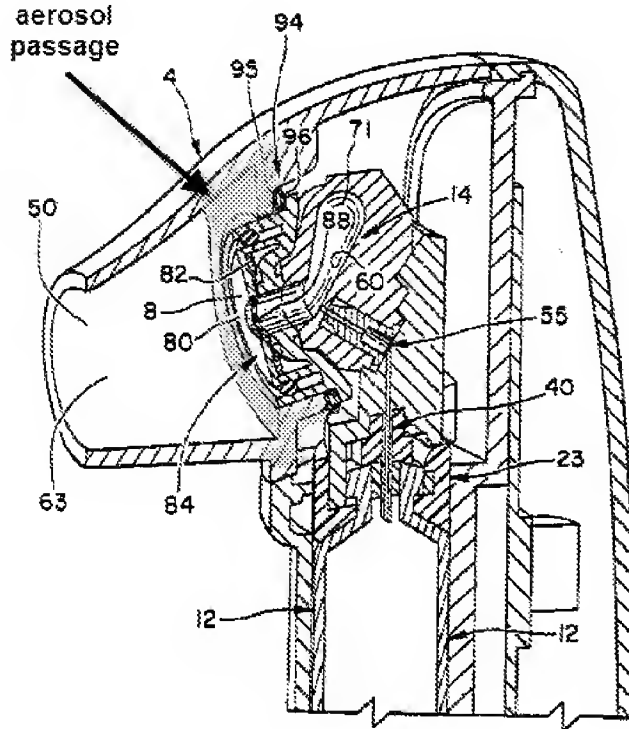
Regarding claim 1, in fig. 8 Patel discloses an inhalation therapy device comprising an aerosol membrane generator 2 having a liquid storage container 14 into which a liquid (Fig. 9) that can be used for therapy is fillable (Fig. 9), having a membrane 88 which is connected on one side with the liquid storage container such that a liquid disposed in the liquid storage container contacts one side of the membrane, and having an oscillation generator 8 for generating oscillations by means of which a liquid disposed in the liquid storage container is nebulised (Col. 2, ll. 45-50, Col. 4, ll.

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66-67-Col. 5, ll. 1-9) into an aerosol through openings (90, Fig. 7) in the membrane (88, Col. 5, ll. 3-9) to the other side of the membrane, a mixing chamber 63 into which the aerosol membrane generator generates the aerosol, having an aerosol passage (see Fig. 8 below), via which the aerosol generated by the membrane generator arrives in the mixing chamber (Col. 4, ll. 62-65), the aerosol passage being disposed with one section on a surface of the aerosol membrane generator so as to surround the membrane along at least one sealing line (Col. 5, ll. 28-29) and extending in an opening manner into the mixing chamber, having at least one breathing air through opening 10 disposed in the region around the aerosol passage (Fig. 1). Patel discloses an aerosol passage and a breathing air through opening, but is silent regarding an inhalation valve disposed in the region around the aerosol passage that opens the breathing air through opening during inhalation and closes the breathing air through opening during exhalation. However, Denyer teaches an inhalation valve (Fig. 2, 94 Fig. 11) disposed in the region around the aerosol passage (Fig. 2) that opens a breathing air through opening (Fig. 2) during inhalation and closes the breathing air through opening during exhalation (Col. 10, ll. 61-63). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Patel's region around the aerosol passage with an inhalation valve and breathing air through opening disposed in the region around the aerosol passage that opens a breathing air through opening during inhalation and closes a breathing air through opening during exhalation, as taught by Denyer, for the purpose of entraining air only during inhalation to protect the

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nebulizer from contaminants. The modified Patel's region around the aerosol passage has a wall section of the mixing chamber (Denyer, Fig. 2, Patel, Fig. 6)

Fig. 8

Regarding claim 2, the modified Patel's region around the aerosol passage discloses a plurality of breathing air through openings (Denyer, Fig. 2).

Regarding claim 3, the modified Patel's region around the aerosol passage includes an inhalation valve, but is silent regarding a surrounding groove. However, Denyer teaches a surrounding groove for the exhalation valve in Fig. 2. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Patel's inhalation valve with the structure of the exhalation valve in

Fig. 2 as well as the surrounding groove structure, for the purpose of providing a better fit for the valve.

Regarding claim 4, the modified Patel's valve element has a bulge (Fig. 2 where the valve hinges) for retention in the surrounding groove.

Regarding claim 5, the modified Patel's nebulizer discloses that the aerosol passage is pipe-shaped (see Fig. 8 above) and the valve element is annular (Denyer, Fig. 2, Patel Fig. 1) and the valve element accommodates the pipe-shaped aerosol passage in the annular opening (Denyer, Fig. 2, Patel Fig. 1).

Regarding claim 6, the modified Patel's nebulizer discloses a surrounding groove (see rejection of claim 3 above) that is provided to accommodate a valve element (Denyer, Fig. 2) in the outer surface of the pipe-shaped aerosol passage (Denyer, Fig. 2, Patel Fig. 1).

Regarding claim 7, the modified Patel's nebulizer discloses a pipe-shaped aerosol passage that is formed by a cylindrical sleeve (walls of aerosol passage in Fig. 8 above), provided on the outer surface of which is a region (Denyer, 3 Fig. 2, Patel Fig. 1) accommodating the breathing air through openings (Denyer, Fig. 2, Patel Fig. 1), which extends essentially perpendicular to the longitudinal axis of the sleeve (Denyer, Fig. 2, Patel Fig. 1).

Regarding claim 8, the modified Patel's nebulizer discloses that the cylindrical sleeve is disposed concentrically to the membrane (see Fig. 8 above).

Regarding claim 9, the modified Patel's nebulizer discloses that the valve element is configured as a circular ring (Denyer, Fig. 2, Patel Fig. 1) and accommodates the cylindrical sleeve in the annular opening (Denyer, Fig. 2, Patel Fig. 1).

Regarding claim 10, the modified Patel's nebulizer discloses that the aerosol passage comprises a bulge (Patel, 84, Fig. 8) in the area facing the membrane.

Regarding claim 11, the modified Patel's nebulizer discloses that the one or more breathing air through openings extend essentially parallel (Denyer, Fig. 2, Patel Fig. 1, Fig. 8 above) to the aerosol passage.

Regarding claim 12, the modified Patel's nebulizer discloses that the breathing air through openings extend in a spiral manner (Denyer, Fig. 2, Patel Fig. 1, Fig. 8 above) in relation to the aerosol passage.

Regarding claim 13, the modified Patel's nebulizer discloses that the one or more breathing air through openings are configured as circular ring sections (Denyer, Fig. 2, Patel Fig. 1, Fig. 8 above).

Regarding claim 14, the modified Patel's nebulizer discloses that the inhalation valve comprises an edge section (Denyer, 2, Fig. 2) which is configured for retaining the inhalation valve (Denyer, Fig. 2), in particular for clamping between a wall of the aerosol generator (Patel 4, Fig. 2) and a wall of the mixing chamber (Patel 1, Fig. 2).

Regarding claim 16, the modified Patel's nebulizer discloses that the breathing air through openings are designed to extend in a sloping manner (Denyer, Fig. 2) such that the breathing air is guided away from the fixing point of the valve element (Denyer, Fig. 2).

Regarding claim 17, the modified Patel's nebulizer discloses that the region (Denyer, Fig. 2, Patel Fig. 1, Fig. 8 above) of the one or more breathing air through openings is disposed essentially on a plane with the membrane (Denyer, Fig. 2, Patel Fig. 1, Fig. 8 above).

4. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. in view of Denyer et al. in further view of Voges (6,443,146 B1).

Regarding claim 15, the modified Patel's nebulizer discloses that the breathing air through openings are provided as well as an aerosol passage, but is silent regarding that the breathing air through openings are provided on all sides around the aerosol passage. However, Voges teaches breathing air through openings (7, Fig. 1) surrounding an aerosol passage. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Patel's breathing air through openings to include breathing air through openings on all sides around the aerosol passage, as taught by Voges, for the purpose of providing more entrained air so the aerosol can better reach the user's lungs.

5. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. in view of Denyer et al. in further view of Abair et al. (4,113,809).

As to claims 18 and 19, the modified Patel's nebulizer discloses a valve element and an inhalation valve, but is silent regarding that they are produced from a resilient material. However, Abair teaches a valve element that is produced from a resilient material (41, Fig. 2, Col. 4, ll. 20). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Patel's

valve element and inhalation valve with a resilient valve element and inhalation valve as taught by Abair, for the purpose of providing ease to the user during inhalation.

Response to Arguments

6. Applicant's arguments filed 3/1/10 have been fully considered but they are not persuasive. On page 9, last paragraph applicant argues that the office action acknowledges that Patel does not reach or suggest an aerosol passage which extends in an opening manner into a mixing chamber, however on Page 4 of the Non-Final rejection mailed on 10/29/09, examiner does acknowledge that Patel discloses an aerosol passage which extends in an opening manner into a mixing chamber. On page 10, first paragraph, applicant argues that Denyer cannot be combined with Patel because it is a different type of nebulizer. However, the inhalation valve of Denyer in figures 2 and 11 are for entraining aerosolized medication to be delivered to the patient (Col. 10, ll. 61-64). Patel already discloses a breathing passage and breathing air through opening and it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the opening with an inhalation valve, as taught by Denyer, for the purpose of controlling when ambient air is brought into the System and to better keep contaminants out of the apparatus while not in use. On page 10, last paragraph, applicant argues that the modified Patel's inhalation valve is not located in the immediate vicinity of the inner aerosol generation, however, as can be seen in Patel's figure 1, air inlet openings 10 are located in the immediate vicinity of the aerosol generated. Finally, applicant argues on page 11, first paragraph that applicant's valve

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and aerosol passage are a single part, however this is not language found in the claims and is therefore irrelevant.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wunderlich et al. (6,176,237 B1) to an inhalation therapy unit with a one way valve opening during inhalation, Cheiman (5,908,158) to an ultrasonic nebulizer with a contact medium and air inlets surrounding the passageway, Stimpson et al. (5,551,416) to an ultrasonic nebuliser with an air inlet. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHEL T. YOUNG whose telephone number is (571)270-1481. The examiner can normally be reached on mon-thurs 7 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/RACHEL T YOUNG/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771